

### **REMARKS**

Applicants thank Examiner Pellegrino for the courtesy of a telephonic interview with the undersigned attorney on October 8, 2004. During the interview, independent claims 10, 19, and 25, and dependent claims 22 and 26 were discussed. During the interview the claim amendments presented herewith were discussed.

### **Status of the Claims**

Before entry of this Amendment and Response, the status of the application is as follows:

- Claim 22 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.
- Claims 25 and 26 are rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter.
- Claims 10, 19, 21, and 23-26 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,876,417 to Devonec *et al.* (hereinafter "Devonec").
- Claims 11 and 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Devonec in view of U.S. Patent No. 4,973,301 to Nissenkorn (hereinafter "Nissenkorn").
- Claims 13-15 and 22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Devonec in view of Nissenkorn and further in view of U.S. Patent No. 6,238,430 to Klumb, *et al.* (hereinafter "Klumb").
- Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Devonec in view of U.S. Patent 5,167,614 to Tessmann *et al.* (hereinafter "Tessmann").

Claims 10-12, 19, 22, 23, and 25 are hereby amended to more clearly describe the nature of the claimed invention. Support for amended claim 10 can be found at least on page 10, and in FIGS. 23-25. Support for amended claims 11 and 12 can be found at least in the first full paragraph on page 12, and in FIGS. 1, 2, and 10-12. Support for amended claim 22 can be found

at least in the first full paragraph on page 11, and in FIGS. 7-9. Support for amended claim 23 can be found at least in the first full paragraph on page 10, and in FIG. 2. Support for amended claim 25 can be found at least in the second paragraph on page 4, the second paragraph on page 10, and in FIG. 23. Applicants submit that the amendments introduce no new matter. Upon entry of this paper, claims 10-15 and 19-26 will be pending and under consideration, with claims 16-17 withdrawn.

#### **Rejections Under 35 U.S.C. § 112**

Claim 22 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants respectfully traverse the rejection of claim 22 to the extent the rejection is maintained over the claim as amended. Specifically, the two occurrences of the term “structure” have been replaced by “flange” and “ledge,” respectively.

#### **Rejections under 35 U.S.C. § 101**

Claims 25 and 26 are rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter. Applicants respectfully traverse the rejection of the claims to the extent the rejection is maintained over the claims, as amended. Specifically, Applicants amended claim 25 to include the language suggested by the Examiner.

#### **Rejections Under 35 USC § 102(e)**

Claims 10, 19, 21, and 23-26 are rejected under 35 U.S.C. § 102(e) as being anticipated by Devonec. Applicants respectfully traverse the rejection of the claims to the extent the rejection is maintained over the claims, as amended.

Independent claims 10, 19, and 25 each recite, in part, a prostatic stent-catheter system including a stent that is sized for placement substantially within the prostatic section of the urethra with its distal terminating end located completely proximal of the external sphincter.

In contrast, Devonec appears to disclose a catheterization means 2 that comprises an upper element 8 and a lower element 9 connected by a deformable connection means 14. See Devonec, col. 4, lines 8-17, and FIG. 1. The upper element 8 is intended to be placed in the upper part of the urethral channel on one side of the striated muscular sphincter (i.e., the external sphincter), and the lower element 9 is intended to be placed in the lower urethral channel on the opposite side of the striated muscular sphincter. See Devonec, col. 4, lines 8-12, and FIGS. 7-9. The distal terminating end of the catheterization means 2 according to Devonec (i.e., lower element 9) is adapted to fit in the bulbar segment of the urethra on the distal side of the external sphincter, and the connection means 14 is adapted to reside in the orifice of the sphincter. See Devonec, col. 4, lines 14-17, col. 7, lines 33-36, and FIGS. 7-9. Nowhere does Devonec teach or suggest a stent with its distal terminating end located completely proximal of the external sphincter.

Additionally, independent claims 10, 19, and 25 each recite, in part, a prostatic stent-catheter system including a connecting segment including a distal end located outside of a patient's body, and a proximal end releasably joined to the distal terminating end of the stent. In one embodiment, a guide is used to join the stent and connecting segment. The guide can be fastened to the proximal end of the connecting segment. The remaining portion of the guide is inserted into the lumen of the stent creating a slip-fit seal between the stent and the connecting segment.

In contrast, Devonec appears to disclose a pusher tube 7 that has an external diameter close to that of the two tubular elements 8, 9 of the catheterization means 2. Also disclosed is a semirigid inner alignment rod 19, whose external cross section is adapted to the internal cross section of the tube 7 and of the catheterization means 2 and whose length is adapted to intubate

both the pusher tube 7 and the catheterization means. See Devonec, col. 4, lines 56-64 and FIG.

2. The pusher tube 7 appears to touch the catheterization means, but is not releasably joined to the distal terminating end of the catheterization means. The semirigid alignment rod 19 ensures alignment of the catheterization means 2 and the introduction means 3. See Devonec, col. 5, lines 43-44. However, the alignment rod 19 is not releasably joined to the distal terminating end of the stent. Both the tube 7 and the rod 19 appear to contact the catheterization means, however neither is joined, releasably or otherwise, to the catheterization means. Nowhere does Devonec teach or suggest a connecting segment that is releasably joined to the distal terminating end of the stent.

In view of these structural differences between Applicants' claimed invention and the device disclosed in Devonec, the prostatic stent-catheter system of the present invention is not anticipated by Devonec.

In view of the foregoing, Applicants submit that amended independent claims 10, 19, and 25 are patentable over Devonec. Because claims 21, 23-24, and 26 depend from independent claims 10 and 25, either directly or indirectly, Applicants respectfully submit that these claims are patentable as well. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

#### **Rejections Under 35 USC § 103(a)**

1. Claims 11 and 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Devonec in view of Nissenkorn. Applicants respectfully traverse with respect to the claims, as amended.

First, amended claims 11 and 12 depend from amended independent claim 10. As discussed above, claim 10 is patentable over Devonec. Nissenkorn fails to cure the deficiencies

of Devonec. Specifically, neither Devonec nor Nissenkorn, alone or in proper combination, teach or suggest a prostatic stent-catheter system including a stent that is sized for placement substantially within the prostatic section of the urethra with its distal terminating end located completely proximal of the external sphincter and a connecting segment including a proximal end releasably joined to the distal terminating end of the stent.

Second, amended claims 11 and 12 are each directed toward a prostatic stent-catheter system that includes a stent having a retaining member extending from the proximal portion of the stent. The retaining member includes a proximal end defining a ledge for receiving a pushing device.

The proximal portion of the Devonec device (i.e., the upper tubular element 8) appears to have a smooth, continuous outer surface. See Devonec, FIGS. 1-12. Devonec does not disclose a retaining element on the upper tubular element 8. Further, Devonec does not suggest the need for a retaining element on the upper tubular element 8, because the upper tubular element 8 is held in place within the urethra by the striated muscle sphincter 13 closing around the connecting element 14. See Devonec, col. 7, lines 33-36.

The intraurethral catheter (IUC) 1 according to Nissenkorn includes a central tubular portion 2 with integral proximal 3 and distal 4 crowns and a hollow inner tube 7 running through its length. See Nissenkorn, col. 2, lines 48-53, and FIG. 1. The proximal crown 3 is intended to sit within the bladder 8 to prevent distal displacement of the IUC 1 (see Nissenkorn, col. 2, lines 58-61, and FIG. 4); however, the proximal crown 3 does not include a proximal end defining a receiving ledge for receiving a pushing device. The IUC 1 is introduced into a patient's urethra by pushing the IUC 1 through a Teflon sheath 30 using an obturator 34. See Nissenkorn, col. 4, lines 18-29. The obturator 34 appears to contact the distal end of the IUC 1 as it pushes the IUC

1 through the Teflon sheath 30 (see Nissenkorn, FIG. 6.); however, Nissenkorn is silent with respect to a ledge, or any other structure, for receiving a pushing device. Nowhere does Nissenkorn teach or suggest a stent that includes retaining member with a proximal end defining a ledge for receiving a pushing device.

As discussed above, there is no suggestion or motivation to add a retaining member to the Devonec catheter, because the catheter of Devonec is held in place within the urethra by another means (i.e., the connecting member 14). In fact, Devonec specifically discloses that the catheter is positioned in relation to the striated muscular sphincter, and not in relation to the neck of the bladder (see Devonec, col. 2, lines 54-61), as disclosed by Nissenkorn. Thus, there is no suggestion or motivation to combine the teachings of Devonec and Nissenkorn and, in fact, Devonec teaches away from adding a retaining member to the proximal end of the catheter that would reside within the bladder neck, as disclosed by Nissenkorn. See, Nissenkorn, FIG. 4.

Furthermore, even if such suggestion or motivation were to exist, which it does not, neither Devonec nor Nissenkorn, alone or in proper combination, teaches or suggests a stent having a retaining member extending from the proximal portion of the stent, wherein the retaining member comprises a proximal end defining a ledge for receiving a pushing device.

In view of the foregoing, Applicants submit that claims 11 and 12 are patentable over Devonec in view of Nissenkorn. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

2. Claims 13-15 and 22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Devonec in view of Nissenkorn and further in view of Klumb. Applicants respectfully traverse the rejection to the claims to the extent the rejection is maintained over the claims, as amended.

Klumb appears to disclose a catheter assembly 2 including a catheter 4 for delivering a stent 38 into a blood vessel of a patient. The stent 38 is a coil-type stent, typically made of nitinol wire, which is wrapped around the catheter shaft 18. See Klumb, col. 6, lines 23-36, and FIGS. 1 and 13-15.

Claims 13-15 depend directly or indirectly from claim 12, which recites, in part, a stent having a retaining member extending from the proximal portion of the stent, wherein the retaining member includes a proximal end defining a ledge for receiving a pushing device. As discussed above, neither Devonec nor Nissenkorn, alone or in proper combination, teaches or suggests a stent having a retaining member extending from the proximal portion of the stent, wherein the retaining member includes a proximal end defining a ledge for receiving a pushing device. Klumb fails to cure this deficiency.

Klumb does not teach or suggest a stent having a retaining member extending from any portion of the stent. Thus, Devonec, Nissenkorn, and Klumb, alone or in proper combination, fail to teach or suggest a stent having a retaining member extending from the proximal portion of the stent, wherein the retaining member includes a proximal end defining a ledge for receiving a pushing device.

Further, claim 22, which depends indirectly from claim 12, recites, in part, a pushing device that includes a flange for engaging the ledge defined by the proximal end of the stent. In contrast, Klumb appears to disclose a proximal end adapter 6 that includes a body 10 to which a push wire manipulator 14 is slidably mounted, a guidewire port 17, and a guidewire 24. See Klumb, col. 5, line 60 to col. 6, line 1 and FIG. 1. The distal end of the guidewire 24 is positioned near a tip 32 of a catheter shaft 18 and is used to help guide tip 32 through the body.

See Klumb col. 6, lines 11-13 and FIG 1. The guidewire 24 includes no structure for engaging the ledge defined by the proximal end of the stent.

As discussed above, neither Devonec nor Nissenkorn nor Klumb, alone or in combination, teach or suggest a retaining member that includes a proximal end defining a ledge for receiving a pushing device. Further, Klumb, alone or in proper combination with Devonec and/or Nissenkorn, also fails to teach or suggest a pushing device that includes a flange for engaging the ledge defined by the proximal end of the stent.

In view of the foregoing, Applicants submit that claims 13-15 and 22 are patentable over Devonec in view of Nissenkorn and Klumb. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

3. Claim 20 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Devonec in view of Tessmann. Applicants respectfully traverse this rejection with respect to the claims, as amended.

As discussed above, Devonec does not teach or suggest a prostatic stent-catheter system including a stent that is sized for placement substantially within the prostatic section of the urethra with its distal terminating end located completely proximal of the external sphincter and a connecting segment including a proximal end releasably joined to the distal terminating end of the stent, as recited in claim 10. Tessmann appears to disclose an elongated tube 11 that has a plurality of unbarbed, unidirectional hook-like projections 16. Tessmann fails to cure the deficiencies of Devonec.

Further, claim 20, which depends directly from amended independent claim 10, recites, in part, a stent having one or more protuberances to aid retention of the body member substantially within the prostatic section of the urethra. Devonec appears to disclose a device that has a



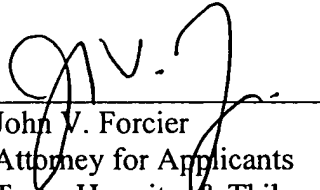
smooth, continuous outer surface. See Devonec, FIGS. 1-12. Devonec does not teach or suggest the need for having one or more protuberances to aid retention of the upper tubular element 8, because the upper tubular element 8 is held in place within the urethra by the striated muscle sphincter closing around the connecting element 14. See Devonec, col. 7, lines 33-36. There is no suggestion or motivation to add protuberances to the Devonec catheter, because the catheter of Devonec is held in place within the urethra by another means (i.e., the connecting member 14). Thus, there is no suggestion or motivation to combine the teachings of Devonec and Tessmann.

In view of the foregoing, Applicants submit that claim 20 is patentable over Devonec in view of Tessmann. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

### CONCLUSION

In view of the foregoing, Applicants respectfully request reconsideration, withdrawal of all grounds of rejection, and allowance of claims 10-17 and 19-26 in due course. The Examiner is invited to contact Applicants' undersigned representative by telephone at the number listed below to discuss any outstanding issues.

Respectfully submitted,

  
John V. Forcier  
Attorney for Applicants  
Testa, Hurwitz, & Thibault, LLP  
125 High Street  
Boston, Massachusetts 02110

Date: November 2, 2004  
Reg. No. 42,545

Tel. No.: (617) 248-7675  
Fax No.: (617) 248-7100

3128808\_1